

MAR 22 2001

K010364
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**510(k) SUMMARY
INVACARE CORPORATION'S
510(k) PREMARKET NOTIFICATION
MIV one 2 one Software**

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6356
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Contact Person: Rae Ann Farrow
Manager, Regulatory Compliance

Date Prepared: February 5, 2001

Name of Device and Name/Address of Sponsor:

MIV one 2 one Software.

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 366-9724

Common or Usual Name
Controller Programming Software

Classification Name
Wheelchair, powered

Predicate Devices

The MIV one 2 one Software is substantially equivalent to the MCC-MIV Micro Computer Controls for Powered Wheelchairs (K94097, June 2, 1994).

Intended Use

The intended use of the MCC-MIV Micro Computer Controls for Powered Wheelchairs is to control powered wheelchair motions and provide a method of selecting the type of operational parameters which best suit the particular control needs of the wheelchair user. The MIV one 2 one Software accessory is a mechanism used to select wheelchair functional performance characteristics.

Technological Characteristics and Substantial Equivalence

Device Description

The **MCC – MIV one 2 one Software** is an optional accessory to the **MCC – MIV Micro Computer Control for Powered Wheelchairs (K940972, June 2, 1994)**. It is a Windows based software application that is used to set wheelchair functional performance characteristics. The application is intended for use with Invacare controllers only and can replace the hand held programmer.

The MIV one 2 one Software is basically a tool for use by the dealer or therapist to access and adjust wheelchair performance parameters. It is not installed on the wheelchair and does not activate or control wheelchair motion.

The MIV one 2 one Software consists of a compact disc containing the software, a custom cable for connecting the controller to the personal computer, and instructions for installing the software. The disc contains the MIV one 2 one-Software and IVS software, which is for electronic trouble-shooting without the use of a modem.

The application is written in Microsoft Visual Basic and is run from a personal computer. Information pertaining to the equipment in use and the applicable driving conditions is used by the application to finely tune the functional performance characteristic settings of the control. The MIV one 2 one software allows the therapist or dealer to personalizes programming information for an individual user, and printout and store the information.

Substantial Equivalence

The MIV one 2 one Software is substantially equivalent to the **Dealer Remote Programmer** optional accessory previously cleared with the **MCC – MIV Micro Computer Controls for Powered Wheelchairs (K94097, June 2, 1994)**. Both have the same intended function and use and both the MIV one 2 one and the Dealer Remote Programmer provide a mechanism to set the wheelchair functional performance characteristics.

The same performance characteristics are programmed with both mechanisms and the potential performance characteristic values that can be selected are the same. No additional performance characteristics or performance characteristic values are available with the MIV one 2 one versus the remote programmer.

The MIV one 2 one differs from the dealer remote programmer in that it runs on a personal computer (PC). Additionally it recommends performance characteristic values based on clinical/function questions. Finally it stores user information, and it can store the program settings on a hard drive or floppy disk.

Performance Data

The MIV controller was previously tested and the results were included in K94097, cleared June 2, 1994. The MIV one 2 one Software does not change the performance of the controller. It is a mechanism, like the remote programmer, that allows the performance parameters for the individual user to be selected.

The testing of the MIV one 2 one was conducted on all combinations of chairs, drives, joystick type, and user types. The testing was conducted to ensure that:

- The performance parameters selected by the MIV one 2 one software matched the performance parameter matrix
- After the performance parameters were selected, the wheelchair functions properly



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Rae Ann Farrow
Manager, Regulatory Compliance
Invacare Corporation
One Invacare Way
P.O. Box 4028
Elyria, Ohio 44036

Re: K010364
Trade Name: MCC-MIV One 2 One Software
Regulatory Class: II
Product Code: ITI
Dated: April 23, 2001
Received: May 8, 2001

Dear Ms. Farrow:

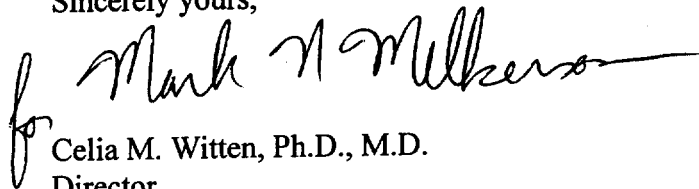
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark A. Milbrink", with a stylized initial "f" to the left.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and
Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): TBD K010364

Device Name: Invacare MCC-MIV one 2 one Software

Indications For Use:

The intended use of the Invacare Model MCC-MIV Micro Computer Controls for Powered Wheelchairs is to control powered wheelchair motions and provide a method of selecting the type of operation parameters which best suit the particular control needs of the wheelchair user. The MCC-MIV one 2 one Software accessory is a mechanism used to select wheelchair functional performance characteristics.

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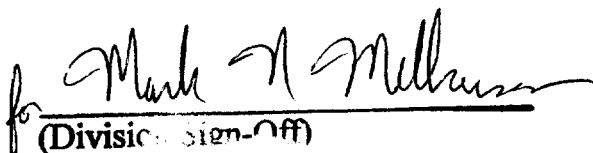
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)


(Division Sign-Off)

Division of General Restorative
and Neurological Devices

K010364
510(k) Number _____